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Food and Drug Administration
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Silver Spring, MD 20993-0002


Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,795,685 was filed on January 11, 2010, under 35 U.S.C. § 156. Please note that the Applicant, Dyax Corp., has also applied for patent term extension for U.S. Patent No. 7,276,480 for the regulatory review period of BLA No. 125277/0 pursuant to the provisions of 37 C.F.R. § 1.785.

The assistance of your Office is requested in confirming that the product identified in the application, KALBITOR® (ecallantide), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).



Mary C. Till
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